

### **Remarks**

Prior to entry of the amendments presented above, claims 1-15 were pending. Claims 3, 5, 14 and 15 have been canceled and claims 1, 4, 8, and 12 have been amended. The cancellation of claims is made herein without prejudice or disclaimer of the subject matter recited therein, and applicants expressly reserve all rights to such subject matter, including the right to file continuation and/or divisional applications. The amendments are fully supported by the specification. Claims 1, 2, 4, and 6-13, including independent claim 1, are thus pending for reexamination and reconsideration, which are respectfully requested in view of the foregoing amendments and following remarks.

In the Office Action mailed February 28, 2003, the Examiner alleged that the subject matter of claims 1-13 was patentably distinct from the subject matter of claims 14 and 15, and required election of one group of claims for examination on the merits. The Examiner also alleged that claims 1-15 are "generic to a plurality of disclosed patentably disclosed species" and required election of a single species for initial examination on the merits. Claim 13 was rejected under 35 USC § 112, first paragraph, for alleged lack of enablement. Claim 1 was rejected under 35 USC § 112, second paragraph, as allegedly indefinite. The specific grounds for rejection, and applicants response thereto, are set out in detail below.

### **Support for amendments**

The amendments to the claims are supported by the original claims. Thus, the amendments to claims 1 and 12 are supported by original claims 3 and 5.

### **Response to Restriction Requirement**

The Examiner alleges that the subject matter of claims 1-13 is patentably distinct from the subject matter of claims 14 and 15, and requires election of one group of claims for examination on the merits. Applicants affirm the prior telephonic election of claims 1-13. The election is made with traverse.

### **Response to Election of Species Requirement**

The Examiner asserts that claims 1-15 are "generic to a plurality of disclosed patentably disclosed species" and requires election of a single species for initial examination on the merits. The Examiner also has "withdrawn from further consideration" certain subject matter from the claims. Although applicants believe that the requirement is improper for the reasons set forth below, the telephonic election of the species of Example 4 for *initial* examination on the merits is affirmed. Claims 1, 2, 6-9, and 11-13 (as amended) read on the elected species.

In the instant case it is improper for the Examiner to withdraw from examination subject matter within the scope of claim 1. It is improper for the Patent Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. See MPEP 803.02. Unity of invention exists within a Markush group where the compounds within the group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. MPEP 803.02. The present claims are directed to hydantoin compounds and methods for making those compounds. The hydantoin ring structure shown in claim 1 represents a substantial structural feature that is essential for the common utility of the compounds as pharmaceutical intermediates. See specification at pages 1-2. Accordingly, unity of invention exists and the claims should be examined in their entirety.

Once unity of invention is established, the procedure for examining Markush claims of the present type is set forth in MPEP 803.02. Briefly, the Examiner should, as here, require an election of species for initial examination on the merits. The provisional election is given effect *only when* the Markush type claim is not allowable over the prior art. In the event that the elected species is found allowable over the prior art, the search should be extended to the extent necessary to examine the Markush claims.

In the instant case, the Examiner required an initial election of species for initial examination on the merits. However, because the elected species apparently were found allowable over the prior art (no prior art is cited in the office action) the scope of examination should be extended as set forth in MPEP 803.02 and it is improper for the Examiner to

"withdraw from consideration" the non-elected subject matter. Accordingly, applicants respectfully request the Examiner to extend the scope of the examination of the invention as presently claimed.

**Rejection under 35 USC §112, First Paragraph**

Claim 13 stands rejected under 35 USC § 112, first paragraph, for alleged lack of enablement. Specifically, the Examiner alleges that the claim term "reacting the compound of formula II with a compound of formula III" encompasses a great number of processes, that there is little predictability in the outcome of the reaction, and therefore that undue experimentation would be required to carry out the claimed process. Applicants respectfully traverse the rejection.

First, applicants note that the rejection apparently is directed at claim 12, rather than claim 13, and assume that the Examiner's reference to claim 13 is a typographical error. Second, applicants respectfully submit that, contrary to the Examiner's allegations, one skilled in the art would readily be able to carry out the process defined in claim 12 without undue experimentation.

Specifically, the specification provides numerous examples of the process defined by claim 12. In each case, the reaction proceeds to give the expected product in good yield with only minor variations in reaction conditions (for example temperature) required to carry out the reaction. One skilled in the art would readily be aware of methods for following the progress of the reaction and could adjust the reaction conditions (such as temperature) as necessary to achieve the desired reaction rate. Such experimentation is entirely routine. The only variable in the starting materials for the process of claim 12 is the nature of the group R', and the skilled chemist would be readily aware of the routine experimentation that would be required to carry out the claimed process for any given R' substituent. Contrary to the Examiner's assertions, nothing in the specification or the art would suggest to the skilled worker that the outcome of the reaction would be anything other than the result taught by applicants' specification, or that anything more than minor variations in reaction conditions would be required to carry out the

reaction. Routine experimentation of this nature is permitted under the standards of 35 USC § 112, first paragraph. See *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). Accordingly, withdrawal of the rejection respectfully is requested.

**Rejection under 35 USC §112, Second Paragraph**

Claim 1 stands rejected under 35 USC § 112, second paragraph, as allegedly indefinite. Specifically, the Examiner asserts that the term "residue of an amino carboxylic acid or of an amino carboxylic acid derivative" is indefinite. Applicants traverse the rejection.

For definiteness, a claim need only reasonably apprise those skilled in the art of the utilization and scope of the invention. *Hybritech, Inc. v. Monoclonal Antibodies*, 231 USPQ 81, 94-95 (1986). Words are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the English language. See MPEP §§ 707.07(g); 2111.01. Claims are to be given their broadest reasonable interpretation consistent with applicants' specification. See MPEP § 2111. In sum, in order to reject the claims on definiteness grounds, it is incumbent on the examiner to show how and why the skilled person having applicants' specification would not be apprised of the invention by the language-at-issue.

In the instant case, applicants respectfully submit that one skilled in the art could readily recognize an amino carboxylic acid and a derivative thereof. Applicants' specification readily demonstrates that the claimed methods are applicable to a wide variety of R' groups, and to restrict the claimed invention to an unduly narrow range of R' substituents would deprive applicants of the full benefit of their inventive effort. Moreover, the Examiner acknowledges that the allegedly objectionable phrase is defined in the instant specification. Accordingly, one skilled in the art is fully apprised of the scope and meaning of the phrase and withdrawal of the rejection respectfully is requested.

Nevertheless, purely to further the claims towards allowance, applicants have amended claim 12 to further define the nature of the amino carboxylic acid. In addition, the claim requires that any free carboxylic acid groups are present in ester form, further defining the nature of the

group R' in the claimed process. Applicants respectfully submit that the claims fully comply with the strictures of § 112, second paragraph and request withdrawal of the rejection.

### CONCLUSION

In view of the above remarks and amendments, it is respectfully submitted that this application is in condition for allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to telephone the undersigned at the number listed below if the Examiner believes such would be helpful in advancing the application to issue.

If any additional fees are required for the filing of this paper, applicants authorize the Commissioner to charge any deficiency to Deposit Account No. 08-1641.

Respectfully submitted,

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By 

Customer No. 26633  
HELLER EHRMAN WHITE &  
MCAULIFFE LLP  
1666 K Street, N.W., Suite 300  
Washington, DC 20006  
Telephone: (202) 912-2142  
Facsimile: (202) 912-2020

Paul M. Booth  
Attorney for Applicant  
Registration No. 40,244